

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW-I

Antimicrobial Program Branch

IN 07-17-89 OUT 08/30/89

Reviewed By Srinivas Gowda ^{WEL} _{7/24/89} Date 08/30/89

EPA Reg. No. or File Symbol 1839-95

EPA Petition or EUP No. None

Date Division Received 04-12-89

Type Product(s): Hospital Disinfectant

MRID No(s) 405725-01

Product Mgr. No. 31 (Lee)

Product Name(s) NP 4.5(D & F)Detergent/Disinfectant

Company Name (s) Stepan Company

Submission Purpose Amendment to add virucidal claim against HIV-1
(AIDS virus) with efficacy data and labeling

Chemical & Formulation Liquid concentrate to be diluted with water

Active Ingredient (s): 8

n-Alkyl (60% C₁₄, 30% C₁₆, 5% C₁₂, 5% C₁₈)
dimethyl benzyl ammonium chlorides.....2.25

n-Alkyl (68% C₁₂, 32% C₁₄)
dimethyl ethylbenzyl ammonium chlorides.....2.25

200.00 Introduction

200.1 Use (s)

Refer to the most recently accepted labeling dated 11-16-88 and proposed labeling dated 04-12-89.

200.2 Current Submission

The current submission is a proposed amendment to add a virucidal claim for the product as a disinfectant against HIV-1 (AIDS virus) with supporting efficacy data and revised labeling.

200.3 Previously Accepted Virucidal Claims: The last accepted label bears virucidal claims for the product against Influenza A₂/Asian, Herpes Simplex Type 1, Adenovirus type 2 and Vaccinia viruses in the presence of a moderate amount of organic soil (5% blood serum) at a 1/256 dilution for a contact time of 10 minutes at room temperature (no re-use).

200.4 Acceptability of Submitted Efficacy Data: Except for the inclusion of dye and fragrance, this product is identical in formulation to NP 4.5, EPA Reg. No. 1839-79. Therefore, the submitted data developed on NP 4.5 are also applicable to NP 4.5 (D & F), at equivalent use concentration.

201.0 Data Summary

201.1 Brief Description of Test (MRID 405725-01)

"Virucidal Efficacy of Stepan NP 4.5." Project No. 6527 by George C. Lavelle, Southern Research Institute, 2000 Ninth Avenue South, P.O. Box 55305, Birmingham, Alabama, 35255, dated 03-15-88.

201.2 Test Summary:

The data were previously summarized in the review for EPA Reg. No. 1839-79 by TSS (Efficacy) dated 10-24-88.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling:

NP 4.5 (D&F) Detergent/Disinfectant is a phosphate free formulation designed to provide effective cleaning, deodorizing and disinfection specifically for hospitals, nursing homes, schools, food processing plants, food service establishments and other institutions where housekeeping is of prime importance in controlling the hazard of cross contamination.

NP 4.5 (D&F) Detergent/Disinfectant, when used as directed, is formulated to disinfect inanimate hard surfaces such as walls, floors, sink tops, toilet bowls, tables, chairs, telephones, and bed frames. For larger areas such as operating rooms, patient care facilities and restrooms, this product is designed to provide both general cleaning and disinfecting.

NP 4.5 (D&F) Detergent/Disinfectant deodorizes those areas which generally are hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, toilet bowls and other areas which are prone to odors caused by microorganisms.

DISINFECTION - To disinfect inanimate, hard surfaces add, 2 ounces NP 4.5 (D&F) Detergent/Disinfectant per gallon of water. Apply solution with a mop, cloth, sponge or mechanical sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, then remove excess liquid.

For heavily soiled areas, a precleaning step is required. Prepare a fresh solution for each use.

To disinfect toilet bowls, flush toilet, add 2 ounces NP 4.5 (D&F) Detergent/Disinfectant directly to the bowl water. Swab the bowl completely using a scrub brush or toilet mop, making sure to get under the rim. Let stand for 10 minutes and flush.

BACTERICIDAL ACTIVITY - When diluted at the rate of 2 ounces per gallon of water, NP 4.5 (D&F) Detergent/Disinfectant exhibits effective disinfectant activity against the organisms: *Pseudomonas aeruginosa* PRD 10, *Escherichia coli*, *Klebsiella pneumoniae*, *Salmonella schultzei*, *Salmonella choleraesuis*, *Streptococcus salivarius*, *Brevibacterium ammoniagenes*, *Streptococcus faecalis*, *Shigella dysenteriae*, *Enterobacter aerogenes* and *Staphylococcus aureus* and meets all requirements for hospital use.

MILDEWSTAT - To control mold and mildew on pre-cleaned, hard, non-porous surfaces add 2 ounces of NP 4.5 (D&F) Detergent/Disinfectant per gallon of water. Apply solution with a cloth, mop or sponge making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application at weekly intervals or when mildew growth appears.

FUNGICIDAL ACTIVITY - At the 2 ounces per gallon dilution NP 4.5 (D&F) Detergent/Disinfectant is also fungicidal against fungi, *Trichophyton mentagrophytes*.

EFFICACY TESTS HAVE DEMONSTRATED THAT NP 4.5 (D&F) DETERGENT/DISINFECTANT IS AN EFFECTIVE BACTERICIDE, FUNGICIDE, AND VIRUCIDE, IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).

Stepan S

Stepan Company
Northfield, IL 60093

NP 4.5 (D & F) Detergent/Disinfectant

CLEANER DETERGENT DEODORIZER MILDEWSTAT (on hard inanimate surfaces)	DISINFECTANT FUNGICIDE (against Pathogenic fungi) VIRUCIDE
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ACTIVE INGREDIENTS

n-Alkyl (60% C ₁₂ , 30% C ₁₄ , 5% C ₁₆ , 5% C ₁₈) dimethyl benzyl ammonium chlorides	2.25%
n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides	2.25%
INERT INGREDIENTS	95.50%
Total	100.00%

EPA REG. NO. 1839-95
EPA EST. NO. 1839-IL-01

KEEP OUT OF REACH OF CHILDREN

DANGER

see side panels for additional precautionary statements

NET CONTENTS

VIRUCIDAL ACTIVITY - NP 4.5 (D&F) Detergent/Disinfectant when used on environmental, inanimate hard surfaces at 2 ounces per gallon of water exhibits effective virucidal activity against Influenza A2/Japan (representative of the common flu virus), Herpes Simplex Type 1 (causative agent of fever blisters and mononucleosis), Adenovirus Type 2 (causative agent of upper respiratory infections), and Vaccinia virus (representative of the pox virus group).

KILLS HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) (AIDS VIRUS) ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

PERSONAL PROTECTION: When handling items soiled with blood or body fluids use disposable latex gloves, gowns, masks, or eye coverings.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of NP 4.5 (D&F) Detergent/Disinfectant.

CONTACT TIME: Allow surface to remain wet for 10 minutes.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS.

DANGER: KEEP OUT OF REACH OF CHILDREN. CORROSIVE. Causes severe eye and skin damage. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. Avoid contamination of food. Remove and wash contaminated clothing.

STATEMENT OF PRACTICAL TREATMENT

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash contaminated clothing before reuse. If swallowed, drink egg whites, gelatin solution or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

STORAGE - Store in a dry place no lower in temperature than 50°F or higher than 120°F.

CONTAINER DISPOSAL - Do not reuse empty container. Triple rinse empty container with water. Return metal drum then offer for recycling or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities. Plastic containers may be disposed of in a sanitary landfill, incinerated, or if allowed by local authorities, by burning. If burned stay out of smoke.

PESTICIDE DISPOSAL - Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

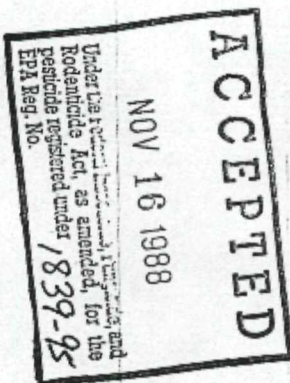
NP 4.5 detergent/disinfectant has been designed specifically for hospitals, nursing homes, schools, food processing plants and other institutions where housekeeping is of prime importance.

DISINFECTION - To disinfect hard inanimate surfaces (such as walls, floors, table tops), add 2 ounces NP 4.5 detergent/disinfectant per gallon of water. Apply solution with mop, cloth, or sponge or mechanical sprayer so as to wet thoroughly. Allow to remain wet for 10 minutes and then let air dry.

To disinfect toilet bowls, flush toilet, add 2 ounces NP 4.5 detergent/disinfectant directly to the bowl water. Swab the bowl completely using a scrub brush or toilet mop, making sure to get under the rim. Let stand for 10 minutes and flush.

For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution for each use.

MILDEWSTAT - To control mold and mildew on pre-cleaned, hard non-porous surfaces (such as floors, walls, table tops) add 2 ounces NP 4.5 per gallon of water. Apply solution with a cloth, mop, or sponge making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application at weekly intervals or when mildew growth reappears.



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

KEEP OUT OF REACH OF CHILDREN. Causes severe eye and skin damage. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. Avoid contamination of food.

STATEMENT OF PRACTICAL TREATMENT

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash contaminated clothing before reuse.

If swallowed, drink promptly a large quantity of milk, egg whites, gelatin solution or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock as well as oxygen and measures to support breathing manually or mechanically may be needed.



NP 4.5 (D & F)

Detergent/Disinfectant

CLEANER	DISINFECTANT
DETERGENT	FUNGICIDE (against
DEODORIZER	pathogenic fungi)
	VIRUCIDE:
MILDEWSTAT (on hard inanimate surfaces)	

ACTIVE INGREDIENTS:

n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18)	
dimethyl benzyl ammonium chlorides	2.25%
n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides	2.25%
INERT INGREDIENTS	95.50%
Total	100.00%

EPA REG. NO 1839-95
EPA EST. NO 1839-JL-01

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panels for additional precautionary statements

Stepan

pan Company

thfield, IL 60093

NET CON

NP 4.5 is a phosphate free concentrated detergent/disinfectant which provides effective cleaning, deodorizing, disinfection, and virucidal activity.

NP 4.5 detergent/disinfectant has been designed specifically for hospitals, nursing homes, schools, food processing plants and other institutions where housekeeping is of prime importance in controlling the hazard of cross contamination.

NP 4.5 when diluted at the rate of 2 ounces per gallon of water is an effective disinfectant against the organism *Pseudomonas aeruginosa* and against all requirements for hospital use. When used as directed, NP 4.5 is formulated to disinfect inanimate hard surfaces such as walls, floors, sink tops, toilet bowls, tables, chairs, telephones and bed frames. For larger areas such as operating rooms, patient care facilities and restrooms, the product is designed to provide both general cleaning and disinfecting.

In addition, NP 4.5 deodorizes those areas which generally are hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, toilet bowls and any other areas which are prone to odors caused by microorganisms.

DISINFECTION - At 2 ounces per gallon dilution, NP 4.5 exhibits effective disinfectant activity against the following:

<i>Pseudomonas aeruginosa</i> PRD-10	<i>Brevibacterium ammoniagenes</i>
<i>Escherichia coli</i>	<i>Streptococcus faecalis</i>
<i>Klebsiella pneumoniae</i>	<i>Shigella dysenteriae</i>
<i>Salmonella schultzei</i>	<i>Enterobacter aerogenes</i>
<i>Salmonella choleraesuis</i>	<i>Staphylococcus aureus</i>
<i>Streptococcus salivarius</i>	

At this level the product is also fungicidal against the pathogenic fungi, *Trichophyton mentagrophytes*.

VIRUCIDAL ACTIVITY: The product when used on environmental inanimate hard surfaces at 2 ounces per gallon of water exhibits effective virucidal activity against Influenza A2-Asian (representative of the common flu virus), Herpes simplex (causative agent of fever blisters and mononucleosis), Adeno virus type 2 (causative agent of upper respiratory infections), and Vaccinia virus (representative of the pox virus group).

EFFICACY TESTS HAVE DEMONSTRATED THAT NP 4.5 IS AN EFFECTIVE BACTERICIDE, FUNGICIDE, AND VIRUCIDE IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).

MOLD AND MILDEWSTAT - NP 4.5 controls mold and mildew and the odors they cause on hard non-porous inanimate surfaces.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE AND DISPOSAL.

STORAGE - Store in a dry place no lower in temperature than 50° F or higher than 120° F.

CONTAINER DISPOSAL - Do not reuse empty container. Triple rinse empty container with water. Return metal drum then offer for reconditioning or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. Plastic containers may be disposed of in a sanitary landfill, incinerated or, if allowed by local authorities, by burning. If burned stay out of smoke.

PESTICIDE DISPOSAL - Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW-II

Antimicrobial Program Branch

EPA Reg. No. or File Symbol 1839-95
Date Division Received 04-12-89
MRID No.(s). 405725-01
Product Manager No. PM-31 (Lee)
Product Name NP 4.5(D & F)Detergent/Disinfectant
Company Name Stepan Company

202.0 Recommendations

202.1 Efficacy Supported By The Data

The data developed on "NP 4.5", EPA Reg. No. 1839-79, are also applicable to support effectiveness of this product which is the same formula with dye and fragrance, as a virucide against HIV-1 (AIDS virus) on hard, non-porous surfaces in the presence of a moderate amounts of organic soil (5% blood serum) when used at a 1/256 dilution for a contact time of 10 minutes at room temperature (20-25°C).

203.0 Labeling

Correct the spelling of *Salmonella schuttmuelleri* to *Salmonella schottmuelleri* and *Shigella dysenteriae* to *Shigella dysenteriae*.

Change Herpes simplex (causative agent of fever blisters and mononucleosis) to read Herpes simplex type 1 (causative agent of fever blisters).

Revise the statement "KILLS HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) (AIDS VIRUS) ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS" to read "KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS)."